NAIMA
NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION

November 3, 1999

Mr. Charles M. Auer
Director, Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W., Mail Code 7405
Washington, D.C. 20460

MR 28751
Ela. 182
6pp

Re: HAPS TEST Rule – Carbonyl Sulfide ("COS")

Dear Mr. Auer:

The North American Insulation Manufacturers Association ("NAIMA") is a trade association of North American manufacturers of fiber glass wool, slag wool and rock wool insulation products. Rock wool and slag wool insulation manufacturers, many of whom are small businesses, may be subject to testing mandated by the Agency's proposed Section 4 Test Rule for 21 Hazardous Air Pollutants because the manufacturing process creates a byproduct identified as carbonyl sulfide ("COS"). NAIMA is writing to urge you and your staff to take maximum advantage of the plan of the National Toxicology Program ("NTP") to test carbonyl sulfide, thereby avoiding substantial practical and legal problems in requiring COS testing under Section 4.

NAIMA has previously submitted formal comments arguing against application of the HAPs Test Rule to rock wool and slag wool producers. Those comments demonstrated that COS as a byproduct of the rock wool and slag wool manufacturing process should not be subject to the HAPs testing program. In addition, NAIMA's comments documented that the majority of COS emissions occur naturally. In addition, NAIMA urged excluding COS from EPA's HAPs testing program because COS has been targeted for testing by the NTP. NAIMA has also met several times with Mr. Hansen and Mr. Sanders regarding the substantial adverse impact of the COS testing proposal on its small business members. Further, NAIMA's comments asserted that EPA failed to comply with both the procedural and substantive requirements of the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA") in adopting the HAPs test rule for COS. NAIMA's submission to EPA demonstrated that the proposed test rule for carbonyl sulfide would have a significant economic impact on a substantial number of small mineral wool manufacturers, which should have triggered EPA's compliance with SBREFA.

NTP should be responsive to EPA's COS data needs. In response to EPA's nomination, the NTP's Executive Committee reviewed and approved on August 1, 1996, an Interagency Committee for Chemical Evaluation and Coordination ("ICCEC") recommendation for extensive toxicological testing of carbonyl sulfide. The NTP stated that "[c]hronic toxicity data for . . . carbonyl sulfide are needed by regulatory agencies in order to set emission standards in compliance with the Clean Air Act Amendments." Further information on NTP's planned testing of COS is provided in the excerpts from the NTP's most recent annual reports (attached).

The NTP further indicates that it plans to conduct inhalation studies for carbonyl sulfide. The NTP will also have the advantage of a toxicokinetic study and a neurotoxicity study of COS produced through the collaborative efforts of the EPA, NIEHS and Duke University Medical Center. In addition, NTP will have access to the preliminary mechanistic studies on COS from Duke University Medical Center.

The EPA actively participates on the NTP's Executive Committee. The Agency has successfully had COS nominated for testing by NTP. Given that NTP has already committed itself to study the potential health effects of COS, EPA should avoid taxing agency and industry resources to conduct any testing until the NTP program is completed.

NAIMA respectfully requests that EPA recognize that rock and slag wool insulation products help promote energy efficiency and prevent pollution by reducing greenhouse gas emissions. By reducing the demand for energy, rock and slag wool insulation products help conserve nonrenewable fuel supplies and reduce the amount of pollutants that are released into the atmosphere through the burning of fossil fuels. Pollutants like carbon dioxide, released when fuel is burned to heat or cool a home, contribute to climate change.

Weighed in the balance the reduction of air pollutants from the use of insulation is far more significant and environmentally beneficial than the testing of a naturally occurring substance that has never been found or suspected of creating any public health risk or environmental problems. Therefore, the Agency should protect the environmental benefits offered by mineral wool companies by eliminating the testing requirement applicable to COS that threatens to bankrupt rock and slag wool insulation companies.

Sincerely,

Angus E. Crane

Angus E. Crane
General Counsel

Attachment

cc: L. Mark Wine
CMA's COS Test Panel
Richard Leukroth

National Toxicology Program

Fiscal Year 1997 Annual Plan

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Review and Approval of Nominations — On January 26, 1996, the NTP Executive Committee reviewed and approved ICCEC recommendations on 11 chemicals nominated to the NTP for extensive toxicological characterization and evaluated by the ICCEC on September 28, 1995. Six of the chemicals— allyl bromide, cellulose insulation, cyanogen chloride, diazoaminobenzene, dimethylaminopropyl chloride HCl, and Stoddard solvent—were recommended by the ICCEC for study, while one, isopropenyl acetate, was recommended for no testing. Four chemicals were reviewed and deferred for further action – chlorate, 1-octene, phenyl glyoxal, and pyridostigmine bromide.

On August 1, 1996, the Executive Committee reviewed and approved ICCEC recommendations on 11 chemicals nominated to the NTP for extensive toxicological characterization and evaluated by the ICCEC on July 15, 1996. Six of the chemicals – chlorate, dibromoacetic acid, carbonyl sulfide, cumene, 1,2-dibromo-2,4-dicyanobutane, and melatonin – were recommended by the ICCEC for study. Two chemicals were recommended for deferral – *tert*-butyl formate and 2,4,6-tribromophenol. Three chemicals previously approved – 12-O-hexadecanoyl-16-hydroxyphorbol-13-acetate (HHPA), methanol, and 1-octene -- were recommended for no testing. The chemicals, nomination sources, and testing or no testing recommendations are given in Table 4 (Appendix A). (CONTACT PERSON: Dr. E. Zeiger, ETP, NIEHS)

Carbon Disulfide, Carbonyl Sulfide

Chronic toxicity data for carbon disulfide (CS_2) and carbonyl sulfide are needed by regulatory agencies in order to set emission standards in compliance with the Clean Air Act amendment. The Pathology Branch, through the ETP, has supported ongoing mechanism-based studies for CS_2, providing critical data for CS_2 risk assessment. An in-house toxicokinetic study for CS_2 and a 13-week in-house neurotoxicity study (a collaborative effort between NIEHS and EPA scientists, and Duke University Medical Center) are complete. The study characterized progression of CS_2 neurotoxicity and dose-response relationships, identified biomarkers of exposure, examined the molecular mechanism of CS_2 peripheral neuropathy, characterized the morphology of the lesions, and correlated neurobehavioral and electrophysiological studies with biomarkers of exposure. Preliminary mechanistic studies with Duke University Medical Center, based on an epidemiological association in humans between CS_2 exposure and increased atherosclerosis, showed that mice on a high-fat diet developed atherosclerotic lesions faster when exposed to CS_2. Data obtained from the short-term studies defined exposures and endpoints for potential long-term CS_2 studies. This collaborative effort will provide relevant mechanistic data useful in the protection of human health.

During the coming year, the CS_2 atherosclerosis study will be completed and a series of these studies will be submitted for publication. A series of papers on the neurotoxicology studies of CS_2 have been submitted for publication.

Currently, inhalation studies for carbonyl sulfide, a metabolite of carbon disulfide, are under design. The thrust of these studies will be to define certain key aspects of the toxicity of carbonyl sulfide such that the larger carbon disulfide database can be used to complete the dataset needed for risk assessment. (CONTACT PERSON: Dr. R. Sills, ETP, NIEHS)

Chloral Hydrate

A. Metabolism and DNA Binding: The objectives of this study were: 1) to characterize and quantify the metabolites of chloral hydrate formed *in vitro* by mouse, rat, and human liver fractions; 2) to determine the mechanism of metabolic activation of chloral hydrate leading to mutations in *S. typhimurium*; 3) to prepare synthetically carcinogen-modified DNA adducts of chloral hydrate and its metabolites; 4) to determine the principal metabolizing enzymes responsible for metabolic activation and DNA binding of chloral hydrate and its metabolites in mice, rats, and humans; and 5) to study mutagenicity, metabolism, and DNA adduct formation of chloral hydrate and its metabolites in transgenic human lymphoblastoid cells expressing cytochrome P450 (CYP) 2E1 and other CYPs, and to determine which human CYP isozyme might be responsible for metabolic activation of chloral hydrate. This study, which was a part of the comprehensive assessment plan for chloral hydrate, has been completed and a technical report will be available the first quarter of FY 1997 (CONTACT PERSONS: Drs. P. Fu, D. Casciano, and F. Kadlubar, NCTR)

B. Effect of Caloric Intake on Metabolism and Toxicity: The purpose of this project is to determine the effects of caloric intake on the subchronic and chronic toxicity, the expression of certain hepatic proteins, and the metabolism and pharmacokinetics of chloral hydrate in B6C3F1 mice. This study will help address the issue of the effect of body weight on the response of rodents to drugs and xenobiotics and will attempt to determine the degree that drug metabolism in rodents will be altered by caloric manipulation to more closely mimic human metabolism. Control B6C3F1 mice

TABLE 4
Chemicals Reviewed by the NTP Executive Committee on January 26, 1996 and August 1, 1996

Chemical (CAS Number)	Nomination Source	Testing Recommendations (Priority)	Rationale/Remarks
Allyl bromide 106-95-6	NCI	carcinogenicity testing	perform carcinogenicity testing
tert-Butyl formate 762-75-4	EPA; private indiv.	toxicity; carcinogenicity testing	deferred pending exposure information
Carbonyl sulfide 463-68-1	EPA	short and long-term toxicity testing	perform short-term toxicity testing; neurotoxicity, ototoxicity and possible carcinogenicity testing
Cellulose Insulation	Private indiv.	in-depth toxicological evaluation; carcinogenicity testing	perform toxicity and carcinogenicity testing
Chlorate 14866-68-3	EPA	carcinogenicity testing	perform carcinogenicity testing
Cumene 98-82-8	NIEHS	carcinogenicity testing	defer to EPA for consideration under TSCA
Cyanogen chloride (CNCl)	EPA	toxicity; carcinogenicity testing	no testing unless CNCl is stable in stomach, or forms products other than cyanide
Diazoaminobenzene 136-35-6	NIEHS	carcinogenicity and toxicity studies	perform metabolism, short-term toxicity, genetic toxicity, and possible subsequent carcinogenicity studies
Dibromoacetic acid 631-64-1	EPA; AWWRF	short-term toxicity; carcinogenicity testing	perform mechanistic, 90-day, reproductive toxicity, and carcinogenicity studies
1,2-Dibromo-2,4-dicyanobutane 35691-65-7	NIEHS	genetic toxicity, short-term toxicity; possible carcinogenicity testing	perform metabolism study to determine need for carcinogenicity test
Dimethylaminopropyl chloride HCl 5407-04-5	NCI	genetic toxicity testing	test for mutagenicity and carcinogenicity
12-*O*-Hexadecanoyl-16-hydroxyphorbol-13-acetate (HHPA) 53202-98-5	Private indiv.	carcinogenicity and cocarcinogenicity testing	no testing because very limited evidence of human exposure
Isopropenyl acetate 108-22-5	NCI	metabolism; in vitro cytogenetics studies	no testing; anticipated metabolism to acetic acid and acetone